



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/027,777	02/23/98	IMMER	P1614-8019

HM12/0623
NIKAIDO MARMELESTEIN MURRAY & GRAM
METROPOLITAN SQUARE
655 FIFTEENTH STREET N W
SUITE 330 G STREET LOBBY
WASHINGTON DC 20005-5701

EXAMINER
VANDER VEGT, F

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/027,777

Applicant(s)

Immer et al

Examiner

F. Pierre VanderVegt

Group Art Unit

1644

☒ Responsive to communication(s) filed on 2/23/98, 5/22/98, 10/23/98 and 5/25/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 is/~~are~~ pending in the application.

Of the above, claim(s) _____ is/~~are~~ withdrawn from consideration.

☐ Claim(s) _____ is/~~are~~ allowed.

☒ Claim(s) 1 is/~~are~~ rejected.

☐ Claim(s) _____ is/~~are~~ objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/~~are~~ objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/737,927.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a divisional of application S.N. 08/737,927 which is a rule 371 continuation of PCT/EP95/02050.

Applicant should amend the specification on page 1 before the beginning of the text to reflect the parent application data above, as well as the status of the '927 parent application.

Claims 2-20 were canceled by Applicant upon filing of the instant application on February 23, 1998.

Claim 1 is currently pending in this application.

Specification

1. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the Applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
 - (b) Cross-References to Related Applications.
 - (c) Statement Regarding Federally Sponsored Research or Development.
 - (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
 - (e) Background of the Invention.
 1. Field of the Invention.
 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
 - (f) Brief Summary of the Invention.
 - (g) Brief Description of the Several Views of the Drawing(s).
 - (h) Detailed Description of the Invention.
 - (i) Claim or Claims (commencing on a separate sheet).
 - (j) Abstract of the Disclosure (commencing on a separate sheet).
 - (k) Drawings.
 - (l) Sequence Listing (see 37 CFR 1.821-1.825).
2. The disclosure is objected to because of the following informalities:

The specification does not contain a brief description of the drawings. It is respectfully suggested that such a section be incorporated into the specification at page 5, before the paragraph which begins "The synthesis of the cardiodilatin fragments" under a header entitled -- BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS--.

Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,767,239 (A on form PTO-892). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 and claim 1 of the '239 patent each claim a process of producing cardiodilatin fragments of the same formula and comprising the same amino acid residues. Both claims are drawn to the same condensation process and carrying out the condensation between the same amino acid residues. The claims are not identical, however, because claim 1 of the '239 patent recites the limitation "preparation of a linear or cyclic cardiodilatin fragment" (column 19, lines 52-53 in particular) which is not a limitation of the instant claim. The claims are not patentably distinct from one another because the claimed invention of claim 1 of the '239 patent is a species of the instantly claimed process and is fully encompassed by instant claim 1.

Claim Rejections - 35 U.S.C. § 112

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

5 Lines 12-13 of claim 1 recite the phrase "characterized in that" but the further limitations imposed by the claim are not characterizations. The term "characterized" in scientific parlance may imply one or more physical steps or procedures to identify a product, but in the case of the instant claims the term is used as a descriptor of the process. It is suggested that the term "characterized in that" be replaced with more common transitional phrases such as --wherein--, --
10 having-- or --further comprising-- as appropriate. Further, the process of condensation of the partial fragments as set forth in lines 14-19 of the claim is ambiguous and unclear in that the claim does not clearly set forth whether two condensations are being performed, one between amino acids Gly¹⁰⁸ and Arg¹⁰⁹ and a second between Gly¹²⁰ and Cys¹²¹, or whether a single condensation is being performed between the junctions of Gly¹⁰⁸-Arg¹⁰⁹ and Gly¹²⁰-Cys¹²¹. Based upon the
15 specification and the fact that the condensation of three partial fragments is claimed, it appears that the former is the correct situation. Further, the differences between the numeration of the condensation sites and the numeration of the central section of the cardiodilatin fragment (ANP(105-121)) is ambiguous and renders the claim unclear. Therefore it is respectfully suggested that the claim be amended to recite following "three partial fragments," in line 14 --R¹-
20 ANP(105-108), ANP(109-120) and Cys¹²¹-R²; with a first condensation of partial fragments ANP(109-120) with Cys¹²¹-R² being carried out between amino acids Gly¹²⁰ and Cys¹²¹ to form the intermediate fragment ANP(109-121)-R² and a second condensation of partial fragment R¹-ANP(105-108) with said intermediate fragment ANP(109-121)-R² being carried out between
25 amino acids Gly¹⁰⁸ and Arg¹⁰⁹ to prepare said cardiodilatin fragments of formula I.--. The suggested amendment finds full support in the instant specification at page 5, third paragraph and clearly defines the partial fragments being condensed in terms of the amino acid residues at the junctions of the partial fragments.

Conclusion

The prior art considered relevant in this case, but not relied upon, consists of US Patent 5, 449,751 (B on form PTO-892), US Patent 5,665,861 (C). The '751 and '861 patents teach cardiodilatin fragments and methods for their synthesis. Neither patent, however, teaches or suggests the method of the claimed invention wherein the synthesis of cardiodilatin fragments is carried out by first separately synthesizing by conventional means three fragments of the peptide and then condensing the fragments to construt the cardiodilatin fragments. The '751 and '861 patents would not suggest to the skilled artisan that it would be advantageous to synthesize the intact cardiodilatin fragment in this manner and do not teach or suggest the claimed invention.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

7. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and even-numbered Mondays (on 1999 365-day calender) from 7:00 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.



F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
June 15, 1999